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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,776	12/17/2004	Hideaki Sasagawa	TOYA107.005APC	5644

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EXAMINER
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JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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02/03/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/518,776	<b>Applicant(s)</b> SASAGAWA ET AL.	
	<b>Examiner</b> Donna Jagoe	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,8-12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,8-12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2010 has been entered.

***Claims 1, 4, 8-12 and 15-18 have been examined on the merits.***

### ***Response to Arguments***

Applicant's amendments and arguments filed October 27, 2010 are acknowledged and have been fully considered but they are not persuasive. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Applicant asserts that Godbey et al. does not teach "ethyl cellulose, hydroxypropyl methylcellulose phthalate or polyacrylate as the polymer and copolymer of ethylene oxide and propylene oxide as the plasticizer. In response, Godbey et al. teach the polymeric film-forming agent include water soluble or water dispersible film forming polymers and oligomers, such as cellulose derivatives including but not limited to hydroxy ethyl cellulose and hydroxy propyl cellulose and acrylates, such as polyacrylate

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(an acrylic resin emulsion) (paragraph 24) and the plasticizer includes pluronic which applicants' specification identifies as having the properties described in instant claim 1 and 18. Applicant asserts that the plastizers included in Godbey et al. falls outside the scope of the claimed invention. In response, a reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). Further, regarding Applicants' assertion that the plasticizer, Pluronic, recited in Godbey et al. does not have the same properties as the plasticizer instantly claimed. It is noted that there are many species of pluronic listed, however, Godbey et al. states generically that Pluronic is one of the plasticizers that is included in the invention and as such, would include the Pluronic F-68. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Applicant states that closed claim language "consisting of" now limits instant claim 1. In

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response, the claim recites "An antifungal medicinal composition, comprising....." The claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. Applicant asserts that Examples of Godbey et al. were hard and could not be removed by washing with water. In response, Godbey et al. teach six blends used to form water-soluble films (paragraph 61). Applicant points to examples in Godbey et al. having less plasticizer than polymeric carrier. In response, Godbey et al. teach, for example polyvinyl alcohol (the film-forming agent) in a final concentration of 5% (see paragraph 64) and The amount of plasticizer present in the carrier recited is from about 1% to about 40% (paragraph 27) which encompasses the instantly claimed amount of 1 to 10 folds with respect to the content of the film forming agent of instant claim 1. Further, a reference is not limited to working examples. Applicant states that the amount of film forming agent instantly claimed in claims 1 and 18 differs from Godbey et al. In response, Godbey et al. teach, for example polyvinyl alcohol (the film-forming agent) in a final concentration of 5% (see paragraph 64) which is encompassed by the claimed 0.1% to 10%. Applicants' point to examples of "hard films" in Godbey et al., however, Godbey et al. also teaches that the flexibility and strength of films made from PVA can be improved by adding low levels of plasticizer (paragraph 66) and also teach application to skin and nails (paragraph 50). In response to Applicants' remarks with regard to example 16 of Godbey et al., a reference is not limited to the working examples, but takes into account the general teaching. The amount of plasticizer can vary in Godbey et al. from 1% to as much as 50% (paragraph 27).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 8-12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al. WO 97/02821 A2 and Godbey et al. Patent Application Publication US 2002/0187181 A1

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The claims are drawn to a pharmaceutical composition comprising the antifungal agent of figures (1) and (2) combined with (A) a film forming agent selected from *inter alia*, ethyl cellulose and (B) a water soluble plasticizer in a form of a solid or a paste at 20°C (68°F or approximately normal room temperature) at 1 atm (normal atmospheric pressure) selected from a polymer or copolymer of oxyethylene and/or oxypropylene and has a polymerization degree of 70 or more. Examples of these film forming agents and plasticizers are provided in the instant specification as "Eudragit" (film-forming agent)" and "Pluronic F68" (plasticizer).

Kodama et al. teach the antifungal agents in figures (1) and (2) (see entire document) for topical application (page 11, lines 14-15). Addressing instant claim 17, examples are provided where the composition is applied to the soles of guinea pigs (page 22, lines 11-22) and provides an example wherein a liquid preparation is applied by painting (page 18, Formulation example 5). Kodama et al. does not teach the specific film forming agents and plasticizers instantly claimed.

Godbey et al. teach a composition comprising a water soluble film forming agent (paragraph 24) and plasticizer (paragraph 26) as a carrier for delivering antifungal pharmaceuticals to skin or nails (paragraph 7 and paragraph 50). The polymeric film-forming agent include water soluble or water dispersible film forming polymers and oligomers, such as cellulose derivatives including but not limited to hydroxy ethyl cellulose and hydroxy propyl cellulose and acrylates, such as polyacrylate (an acrylic resin emulsion) (paragraph 24) and a plasticizer such as a random copolymer of ethylene oxide and propylene oxide or block copolymer of ethylene oxide and propylene

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oxide such as Pluronic (paragraph 26). Applicant's specification teaches that Pluronic meets the limitations of the plasticizer in instant claims 1 and 18. The amount of plasticizer present in the carrier recited is from about 1% to about 40% (paragraph 27) which encompasses the instantly claimed amount of 1 to 10 folds with respect to the content of the film forming agent of instant claim 1. Addressing the limitation of instant claim 1, drawn to the content of the film forming agent in the composition of 0.1% to 10% by weight in volume, Godbey et al. teach, for example polyvinyl alcohol (the film-forming agent) in a final concentration of 5% (see paragraph 64) which is encompassed by the claimed. The active agent includes antifungal agents (paragraph 47) for delivery to fingernails or toenails or treatment to the skin with antifungal agents (paragraph 50). Addressing instant claims 9 and 10, drawn to the further inclusion of an anionic surfactant, Godbey et al. teach the inclusion of a surfactant such as an anionic surfactant (paragraph 40). Specific surfactants include, without limitation, C8 to C22 alkyl ether ethoxylates, C8 to C22 alkyl ester ethoxylates, sorbitol C8-C22 alkyl esters, sorbitol C8 to C22 alkyl ester ethoxylates, and mixtures including one or more of the foregoing. Addressing instant claims 12 and 18, Godbey et al. does not specifically teach acetone as a further organic solvent, however, it teaches an organic solvent. (paragraph 39 and claim 40). Acetone is a well-known organic solvent for diluting nail varnish and it would have been obvious to one having ordinary skill in the art to employ acetone as a solvent in the composition. Godbey et al. does not teach an antifungal composition wherein the antifungal composition is capable of "recoating" (claim 15) however, Kodama et al. teach the antifungal medicament of formula (1) and (2) for



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painting (page 18, example 5) and Godbey et al. teach the same carrier in a film for coating nails or skin with an antifungal agent (paragraph 50). It does not teach recoating, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to recoat (repaint) the formulation when necessary to reapply an antifungal film for effective treatment. Regarding the antifungal medicinal composition wherein the coating is removable by swelling means or physical scratching, none of the references teach this limitation, however, Godbey et al. teach that the formulation is a water soluble or water dispersible film (paragraph 32) and as such would be swellable and is capable of being removed by physical scratching. Godbey et al. teach application to fingernails and toenails. Regarding the limitation of the coating film being maintained on a skin or nail surface for at least 12 hours from drying after application and removable with water, as stated supra, Godbey et al. teach that the antifungal film is water soluble or water dispersible and as such, could be maintained on the skin or nail surface provided it is not exposed to water.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper “functional approach” to the determination of obviousness as laid down in *Graham*. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

Exemplary rationales that may support a conclusion of obviousness include:

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- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Based on the teachings of the MPEP and KSR above, by employing the rationale in (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to formulate film forming formulations with plasticizers to maintain flexibility from the teaching of Godbey et al. who teach a formulation comprising water

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soluble film forming agents combined with plasticizers such as pluronic (paragraphs 24-26) teach that these flexible films are suitable for incorporating medicinal agents such as antifungal agents for application to nails and skin combined with the teaching of Kodama et al. who teach the antifungal agents in figures (1) and (2) (see entire document) for topical application (page 11, lines 14-15) and teach examples where the composition is applied to the soles of guinea pigs (page 22, lines 11-22) and provides an example wherein a liquid preparation is applied by painting (page 18, Formulation example 5). One having ordinary skill in the art could have employed the antifungal agent used for topical application and for "painting" recited in Kodama et al. with the formulation of a film forming agent and plasticizer of Godbey et al. for applying the antifungal formulation to skin and nails, and the results would have been predictable. Godbey et al. teach an effective film-forming carrier and suggest that it would be effective to apply antifungal agents for application to skin and nails. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the antifungal agent taught in Kodama et al. in the film-forming agent/plasticizer formulation of Godbey et al. for the predictable result of effective treatment of nail fungus or skin fungus.

A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35

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U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./  
Examiner  
Art Unit 1619

December 16, 2010

/Robert A. Wax/  
Supervisory Patent Examiner  
Art Unit 1615